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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/048,212	06/07/2002	Atsushi Miyamoto	Q68293	4780

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EXAMINER	
COOK, LISA V	

ART UNIT	PAPER NUMBER
1641	

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01/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/048,212	MIYAMOTO ET AL.	
	Examiner	Art Unit	
	Lisa V. Cook	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-6,9 and 10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-6,9 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/07 has been entered.

Amendment Entry

2. Applicants response to the Final Office Action mailed 02 August 2007 is acknowledged (Paper filed 10/31/07). In the amendment filed therein, claims numbered 1 and 6 were modified. Claims 2, 3, 7, and 8 were canceled without prejudice or disclaimer. Currently, claims 1, 4-6, and 9-10 are pending and under consideration.

3. Objections and/or rejection of record not reiterated herein have been withdrawn.

REJECTIONS MAINTAINED

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

I. Claims 1, 4, 6, and 9 are rejected under 35 U.S.C.103(a) as being unpatentable over Hunter et al. (Int. Arch. Allergy, 36 354-375, 1969) in view of Dosa et al. (Immunology, 1979, 38, pages 509-517) and further in view of Scherr (US Patent #4,096,138).

Hunter et al. teach agglutination procedures to measure antibody-antigen binding. In one embodiment, pepsin treated antibodies are coupled to BSA (protease treated BSA) and use to measure antigen interaction via agglutination. See pepsin of F(ab)2 fragments and 7S on page 356; page 363. Bovine serum albumin (BSA) is proven useful in being coupled to reagents while the reagent binding ability in agglutination procedures is maintained. See page 361 number 2 and table IV.

Hunter et al. are silent with respect to the pepsin digest rendering fragmented BSA. However, Dosa et al. disclose the effect of peptic degradation on the immunological and antigenic properties of bovine serum albumin (BSA). See abstract. BSA was digested with pepsin and the fluorescence-binding efficiency evaluated. The BSA fragments obtained from a digest did not form BSA-anti-BSA immune complexes (see page 511-512) and did not interact with B cells (see page 516, 1st column 1st paragraph).

The systematic degradation of BSA with pepsin provided an excellent model for investigating the function and nature of different antigenic determinants present on protein antigens. Page 515, 2nd column – Discussion.

Hunter et al. discloses the claimed invention except for the fragmented BSA produced from pepsin digestion.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to degrade BSA with pepsin thereby producing fragmented BSA because Dosa et al. taught that the systematic degradation of BSA with pepsin provided an excellent model for investigating the function and nature of different antigenic determinants present on protein antigens. Page 515, 2nd column – Discussion.

Hunter et al. in view of Dosa et al. differ from the instant invention in not specifically teaching the utility of BSA coated latex particles carrying an antibody or antigen specifically reactive with the analyte of interest.

Scherr teach this limitation. Specifically, Scherr disclose immunological test procedures. The agglutination tests involving proteins coupled to particles. See column 1 lines 24-43. The use of BSA coated surfaces is taught to eliminate spatial interference due to steric hindrance (Applicant's reduce a non-specific reaction). See column 2 lines 38-68.

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to use a BSA coated latex assay as taught by Sherr with the BSA protease pre-treatment method of Hunter et al. in view of Dosa et al. because Sherr taught The use of BSA coated surfaces is taught to eliminate spatial interference due to steric hindrance. See column 2 lines 38-68.

One of ordinary skill in the art would have been motivated to use BSA coated latex in order to reduce interferences.

Response to Arguments

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues that the rejection is overcome and/or traversed at least because Dosa et al. does not teach that fragmented BSA consisting essentially of 2 to 9 fragments that are capable of preventing a non-specific reaction of latex particles. This argument was carefully considered but not found persuasive because the cited prior art teaches the same reagents required by the instant claims and the disclosure (BSA treated with pepsin). More specifically, as contended by Applicant (see page 8 -last paragraph of the response filed 6/4/07), Dosa et al. teach conditions at 6 minutes with pepsin BSA is cleaved into 10 to 11 fragments (which reads on the instant claims consisting essentially of 2 to 9 fragments).

Also, it is worth noting that Dosa et al. teach multiple time periods of pepsin digestion ranging from 3 min to 360 min. Absent evidence to the contrary the reagents taught by Dosa et al. would produce BSA peptide constructs consisting essentially of 2 to 9 fragments. Further, it has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.

The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In re Herz, 537 F.2d 549, 551-52,190 USPQ 461, 463 (CCPA 1976). Although the cited reference of Dosa appears to read on more fragments (10 to 11), the claims are open to more fragments as long as they do not materially effect the claimed invention. Since the claimed invention is drawn to the same fragments they do not materially affect the basic and novel characteristic(s)" of the claimed invention. This is supported by the disclosure on page 5, wherein different fragments are taught.

Dosa et al. is cited in combination with Hunter et al. and Scherr to make obvious the use of "protease (pepsin) treated fragmented bovine serum albumin" in latex particle agglutination procedures. *A priori,* it would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to use a BSA coated latex assay as taught by Sherr with the BSA protease pre-treatment method of Hunter et al. in view of Dosa et al. because Sherr taught The use of BSA coated surfaces is taught to eliminate spatial interference due to steric hindrance. See column 2 lines 38-68. One of ordinary skill in the art would have been motivated to use BSA coated latex in order to reduce interferences.

Applicant contends that Dosa et al. do not teach fragmented BSA consisting essentially of about 2 to 9 fragments. This argument was carefully considered but not found persuasive because Dosa et al. utilize the same fragmenting agent (pepsin) as the specification (Example1). The use of pepsin at a concentration that produces about 2 to 10 fragments of BSA would have been obvious to one having ordinary skill in the art at the time the invention, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

II. Claims 5 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunter et al. (Int. Arch. Allergy, 36 354-375, 1969) in view of Dosa et al. (Immunology, 1979, 38, pages 509-517) and further in view of Scherr (US Patent #4,096,138) as applied to claims 1, 4, 6, and 9 above, and further in view of Nakase et al. (JP 48019719 Abstract Only).

Please see Hunter et al. in view of Dosa et al. and further in view of Scherr as set forth above. Hunter et al. in view of Dosa et al. and further in view of Scherr. disclose the reagent combination involving protease treatment in combination with BSA and antigen/antibody coated BSA latex particles. However, Hunter et al. in view of Dosa et al. and further in view of Scherr do not teach the use of these reagents for anti-streptolysin O antibodies.

Nakase et al. disclose that the addition of BSA (bovine serum albumin) to streptolysin O stabilizes streptolysin O and allows streptolysin O to maintain its activity. See abstract.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to take the protease treatment in combination with BSA and antigen/antibody coated latex particles detection reagents as taught by Hunter et al. in view of Dosa et al. and further in view of Scherr and utilize them in turbidity measurements for anti-streptolysin O antibodies/antigen assays because Nakase et al. disclose that the addition of BSA (bovine serum albumin) to streptolysin O stabilizes streptolysin O and allow streptolysin O to maintain its activity. See abstract.

Response to Arguments

Applicants contend that the rejection is traversed and/or overcome because Nakase et al. does not supply the deficiencies in Dosa et al. This argument was carefully considered but not found persuasive because Dosa et al. is maintained. The arguments against Dosa et al. are addressed above. For the reasons noted herein, the rejections are maintained.

5. For reasons aforementioned, no claims are allowed.

Remarks

6. Prior art made of record and not relied upon is considered pertinent to the applicant's disclosure:

A. Masson et al. (EPO 0 061 857 A1) disclose pepsin digestion to eliminate protein interferences. See page 8 lines 25 through 30.

7. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group TC 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see httpr//pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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